K112219/S
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# 510 (k) SUMMARY

NOV 18 2011

Applicant and Manufacturer

ThermopeutiX, Inc.
9951B Businesspark Avenue
San Diego, California 92131
Phone: (858) 549-1760
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Contact Person

Thomas Schroeder, Director, RA/QA

Device Classification

| | |
|---|---|
| Common Names: | Vascular Clamp, Temporary Occlusion Catheter |
| Classification Name: | Devices of this type are classified as Class II under 21 CFR Part CFR Part 870.4450, Vascular Clamp (Product Code MJN). |
| Proprietary Name: | TAPAS™ Catheters |

Predicate Device

The Predicate device is the ThermopeutiX DuoFlo™ catheter cleared via 510k's K080700 and K093647.

TAPAS™ Catheter

The ThermopeutiX TAPAS™ Catheter utilizes the identical materials, design and construction methods that are used in the fabrication of DuoFlo™ catheter. These materials and construction methods have met applicable biocompatibility and shelf life requirements. The ThermopeutiX TAPAS™ Catheter has the same intended use as the DuoFlo™ catheter except that the extracorporeal connection option was deleted and a second balloon was added. The same contraindications that apply to the DuoFlo™ catheter apply to the TAPAS™ catheter.

Indications for Use

The ThermopeutiX TAPAS™ Catheter is intended for general intravascular use in the peripheral vasculature in arteries 1.8 mm and larger. Once placed in the selected region, the catheter can be used for infusion of diagnostic and/or therapeutic agents, and for controlling blood flow to the selected region. The diagnostic and/or therapeutic agents are to be used in accordance with specifications outlined by the manufacturer.

The TAPAS™ Catheter is contraindicated for use in the coronary and intracranial arteries.
The TAPAS™ Catheter is not intended for embolic protection or as an aspiration catheter.

Device Description

Other than deletion of an optional extracorporeal circuit connection and the addition of a second balloon, the TAPAS™ catheter that is the subject of this submission is a substantially equivalent to the predicate ThermopeutiX DuoFlo catheter. The TAPAS™ catheter, as does the DuoFlo™ catheter, consists of two coaxial tubular shafts (inflow and outflow lumens) that can infuse diagnostic and/or therapeutic agents to selected regions, as well as direct arterial blood or other solutions to a specific region or organ. The lumens may be accessed using external devices connected to these lumens. There are three additional smaller lumens; one lumen is used for inflation of the distal balloon on the inflow lumen, one is for optional pressure monitoring and the third lumen permits inflation of the balloon on the outflow lumen.

Technological Characteristics Comparison

The TAPAS™ Catheter utilizes the same design, construction, materials and processes as the DuoFlo catheter with no technological differences. The TAPAS™ catheter features smaller shaft sizes and a second occlusion balloon on the outflow lumen (shaft).

Performance and Safety

The biological safety of the device has been demonstrated through biocompatibility studies of patient contact materials in accordance with the standards outlined in ISO 10993-1. Physical testing was performed and results were in compliance with relevant standards and the product specification. The following non-clinical tests were performed and results were acceptable;

- Tip and shaft dimensions
- Balloon compliance and inflation volume
- Balloon Inflation and deflation times
- Balloon fatigue
- Balloon burst
- Balloon bond strength
- Shaft/lumen joint bond strength
- Sheath compatibility
- Shaft kink
- Shaft torque
- Shaft burst pressure
- Tip bond strength
- Concentric shaft movement
- Manifold lumen joint strength
- Stopcock lumen joint strength

The device is supplied sterile and was adopted into an existing validated ethylene oxide sterilization cycle. Sterility conforms to a Sterility Assurance Level (SAL) of $10^{-6}$. The supplied instructions for use provide the user with the applicable warnings and cautions during use. There are no new safety or effectiveness issues related to this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

ThermopeutiX, Inc
c/o Mr. Thomas P. Schroeder
Director, RA/QA
9951B Businesspark Avenue
San Diego, CA 92131

NOV 18 2011

Re: K112219
Trade Name: TAPAS Catheters
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: MJN
Dated: October 24, 2011
Received: October 27, 2011

Dear Mr. Schroeder:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K112219

Device Name: TAPAS™ Catheter

Indications for use: The ThermopeutiX TAPAS™ Catheter is intended for general intravascular use in the peripheral vasculature in arteries 1.8 mm and larger. Once placed in the selected region, the catheter can be used for infusion of diagnostic and/or therapeutic agents, and for controlling blood flow to the selected region. The diagnostic and/or therapeutic agents are to be used in accordance with specifications outlined by the manufacturer.

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The TAPAS™ Catheter is not intended for embolic protection or as an aspiration catheter.

Prescription Use: ____X____ AND/OR Over-the-counter Use: _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K112219